

### **ATTACHMENTS**

Attached hereto is a terminal disclaimer over claims 1-3 and 11 of U.S. Patent 7,273,887 in response to a rejection on the grounds of nonstatutory obviousness-type double patenting.

Attached hereto is a terminal disclaimer over claims 1-3 and 27 of U.S. Patent Application 11/835,500 in response to a provisional rejection of the pending claims on the basis of nonstatutory obviousness-type double patenting.

### **REMARKS**

This amendment is submitted in response to the Office Action at Paper No. 20080118 and includes amendment to improve preamble form of claims 25-30. Claims 19, 20, and 24-34 are submitted for reconsideration.

Claims 19, 20, 24, 26, 27 and 30-34 stand rejected under 35 U.S.C. §103(a) as being obvious over Mantelle (US 5,446,070). Lastly, claims 25, 28 and 29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mantelle in view of Swinchart (US 5,961,997).

#### **Remarks Directed to Rejection of Claims 19, 20, 24, 26, 27 and 30-34 under 35 U.S.C. §103 as Being Obvious over Mantelle**

The basis of this rejection is that Mantelle teaches with respect to Examples 25 and 28 all the claim limitations with the exception that a second anesthetic is not provided as a free base of the second anesthetic, as would be required by the pending claims (Paper No. 20080118, page 5, first full paragraph). The outstanding rejection cites with particularity column 8, lines 53-65 of Mantelle which states:

In particularly preferred embodiments of this invention, the free base local anesthetic agent is selected from the group comprising lidocaine, procaine, propoxycaine, mepivacaine, prilocaine, dyclonine, pramoxine, benzocaine and chloroprocaine. The salt form is preferably one selected from the group comprising prilocaine, tetracaine, bupivacaine, dyclonine, dibucaine, etidocaine and lidocaine salts. The aforementioned bases and salts can be used alone or in combination with other anesthetic bases

and salts as needed to achieve therapeutically effective levels when administered transdermally, or through other topical route.

The outstanding rejection also cites the boilerplate found in Mantelle at column 23, lines 24-36 in recognition that one of ordinary skill in the art can make modifications and variations without departure from the spirit and scope of the invention.

The basis of the rejection is that "It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the second anesthetic salt with a free base of the anesthetic or with a second therapeutic agent." The motivation for doing so being based on Mantelle found at column 23, lines 24-36, that any of the following drugs could be substituted for the anesthetic agent as the pharmacologically active agent and hence "a skilled artisan would have reasonable expectation of success in achieving the safest clinical outcome substituting the second anesthetic salt with a free base of the anesthetic or with a second therapeutic agent." (Paper No. 20080118, paragraph spanning pages 5-6).

As a matter of claim construction, it is noted that the pending claims submitted for reconsideration use the close ended transitory phrase "consisting of" with respect to the components of the anhydrous gel anesthetic formulation. Applicant is in agreement that the compositions of Mantelle contain an anesthetic salt and therefore not prior art relevant to the patentability of the pending claims. It is submitted that Mantelle with respect to anesthetic compositions always has an anesthetic base and an anesthetic salt of a different structure (e.g. col. 6, 33-39).

With respect to the rejection basis that an anesthetic salt is itself optional or replaced with an anesthetic base relies on the statement found in Mantelle at column 8, lines 60-64.

It is respectfully submitted that this sentence has been misinterpreted as pertaining separately to anesthetic bases and salts as being amenable to use of either one alone. Applicant

submits that this sentence is appropriately read as “The [(aforementioned bases and salts [together as a unit] can be used alone)] or in combination with other anesthetic bases and salts as needed to achieve therapeutically effective levels when administered transdermally, or through other topical route.” As such, it is submitted that a proper reading of this statement consistent with the specification as a whole is that the anesthetic base and salt are always present with at least one anesthetic base and one anesthetic salt always being present. Support for Applicant’s interpretation as to the reading of Mantelle is found throughout and includes column 4, lines 4-13; column 4, line 45 – column 5, line 2; column 5, lines 32-62; column 6, lines 32-39; column 9, lines 52-68; column 11, lines 1-12; column 14, lines 4-23; and claims 26-45. In particular, the table depicted at column 14, lines 4-23 nowhere provides a formula with anesthetic salt that is not present. As such, it is respectfully submitted that a fair reading of Mantelle is that an anesthetic salt is always present in an anesthetic formulation. Indeed, statements found in Mantelle such as that found at column 4, lines 19-21 “Furthermore, the combination of the salt and base forms [of the anesthetic], advantageously results in rapid onset of anesthetic action with prolonged anesthetic effect.” Applicant respectfully submits that such statements not only teach the criticality of the salt base but in fact represent a teaching away from the claimed formulation lacking the anesthetic salt.

The claimed invention recites just the contrary to the teachings of Mantelle in including as an anesthetic only an anesthetic base. As such, it is respectfully submitted that one of ordinary skill in the art upon reading Mantelle would always include an anesthetic salt and as such the pending claims are submitted for reconsideration. Additionally, the pending specification recites an attribute of the claimed invention that the anesthetic provided per the pending claims does not penetrate into the systemic circulation (see page 4, line 1). As this

attribute of the claimed invention is neither taught nor contemplated in Mantelle, further differentiates the claimed invention.

With respect to the ultimate basis for the outstanding rejection, namely the replacement of the anesthetic salt with a second therapeutic agent, Applicant submits that the drug substitution provided with respect to column 23, lines 32-36 of Mantelle replaces the anesthetic agent which upon a fair reading of the text provided in Mantelle at column 6, lines 19-51 indicates that the anesthetic agent is in fact a combination of an anesthetic base along with an anesthetic salt of another anesthetic structure. Additional support for Applicant's reading of column 23, lines 32-36 is found with respect to Examples 29-36 in which a combination of anesthetic base and anesthetic salt are now replaced by one of the therapeutics enumerated at columns 23-41. Nowhere does Mantelle teach or even contemplate a composition containing a base anesthetic and a second therapeutic agent, and as such Applicant submits that one of ordinary skill in the art would not have the motivation articulated in the outstanding rejection to produce such a composition. Rather, Mantelle teaches replacement of anesthetics with another therapeutic in the context of a formulation containing a bioadhesive. See again Examples 29-36 of Mantelle in support of Applicant's position. This reading of Mantelle coupled with the claim "consisting of" transitory phrase, justify reconsideration of the outstanding rejection.

In light of the above remarks, reconsideration and withdrawal of the rejection as to claims 19, 20, 24, 26, 27 and 30-34 under 35 U.S.C. §103(a) over Mantelle is requested.

**Remarks Directed to Rejection of Claims 25, 28 and 29  
under 35 U.S.C. §103(a) over Mantelle in View of Swinehart**

The basis of the rejection is that Mantelle teaches the claim limitations with the exception of a composition containing lidocaine present from 0.5 to 6 total weight percent or an anti-itch agent with Swinehart being provided to bolster these deficiencies of Mantelle.

Applicant submits that pending claims 25, 28 and 29 are allowable on the basis of dependency from independent claim 19 (claims 25 and 28) and independent claim 24 (claim 29). Independent claims 19 and 24 are now believed to be in allowable form on the basis of the above remarks. As such, these claims dependent therefrom are likewise submitted to be in allowable form. Reconsideration and withdrawal of the rejection as to claims 25, 28 and 29 under 35 U.S.C. §103(a) over Mantelle in view of Swinehart is respectfully requested.

**Remarks Directed to Double Patenting**

All of the pending claims stand rejected as being unpatentable over claims 1-3 and 11 of U.S. Patent 7,273,887.

A terminal disclaimer is provided herewith that upon entry is believed to overcome this rejection on the basis of nonstatutory obviousness-type double patenting.

All of the pending claims stand rejected as being unpatentable over claims 1-3 and 27 of U.S. Patent Application 11/835,500.

A terminal disclaimer is provided herewith that upon entry is believed to overcome this rejection on the basis of nonstatutory obviousness-type double patenting.

**Summary**

Claims 19, 20 and 24-34 remain pending in the application. Each of these claims is submitted to be in allowable form and directed to patentable subject matter. Reconsideration and withdrawal of the outstanding rejections and the passing of this application to allowance are solicited.

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Respectfully submitted,

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